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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,447	06/09/2000	Steven Neville Chatfield	KCO1003US	4359

7590 10/06/2003

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	23

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/591,447	Applicant(s) CHATFIELD ET AL.	
	Examiner Ja-Na Hines	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *1,7-17,20,25,27 and 31-41*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 2. NOTE: The after final amendment will not be entered because it raises issues that require further consideration, does not overcome the standing rejections and presents additional claims without cancelling a corresponding number of finally rejected claims. Neither the specification nor originally presented claims provides support for a composition comprising a pathogenic bacterium attenuated by a defined mutation in the surA gene and carrier. The surA mutation has not been defined, rather the specficiation defines mutations in general.

The rejection of record over claims 1,7-17, 20, 25, 27 and 31-41 under 35 U.S.C. 103(a) as being unpatentable over Lazer et al., (1996) in view of Dougan et al (US patent 5,527,529) is maintained. The rejection was that it would have been prima facie obvious at the time of applicants' invention to modify the pathogenic bacteria comprising a mutation in the surA gene as taught by Lazar et al., to further include mutations in one or more outer membrane regulation genes as taught by Dougan et al., who already teach that bacteria comprising such mutations was well known in the art and no more than routine skill would have been required to produce said attenuated bacteria. Applicants argue tha Lazer et al., and Dougan et al., is nonanalogous art. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, no more than routine skill would have been required at the time of applicants' invention to have used well-known compositions and well known methods of invoking an immune response comprising attenuated comprising well-known mutations in pathogenic gram-negative bacterium that may be genetically altered to achieve well-known results. Moreover, one would have a reasonable expectation of success in mutating attenuated bacterium since the prior art already teaches mutations in genes which control outer membrane proteins.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious at the time of applicants' invention to modify the pathogenic bacteria comprising a mutation in the surA gene as taught by Lazar et al., to further include mutations in one or more outer membrane regulation genes as taught by Dougan et al., who already teach that bacteria comprising such mutations was well known in the art and no more than routine skill would have been required to produce said attenuated bacteria.